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EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
06/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,621	JENSEN ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-20,43-46,54-69,73-82,105,106,110-113 and 132-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-20,43-46,54-69,73-82,105,106,110-113 and 132-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on March 1 2010 is acknowledged. Claims 1-9, 21-42, 47-53, 70-72, 83-104, 107-109, 114-131 and 137-189 were/stand cancelled. Claims 10, 18-20, 43, 69, 78, 105-106 and 132-134 were amended. Claims 10-20, 43-46, 54-69, 73-82, 105-106, 110-113 and 132-136 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Rejections Necessitated by the Amendments filed March 1 2010

Claim Objections

The claims are objected to because the lines are crowded too closely together, making reading difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

Maintained Objections/Rejection

Specification

The amendment filed May 29 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “has lower

correlation". Applicants' amendment is attempting to incorporate this language into the specification. However, this language or idea was not present in the application at the time of filing.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 110-112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 110-112 introduce new matter as the claims recite the limitation: "lower correlation". There is no support in the specification for this limitation. The limitation of: "lower correlation" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses the tests being highly correlated with the supplement but does not describe the instantly claimed limitation. There is no guidance

in the specification to select lower correlation and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Response to Arguments

Applicants argue that the term "lower correlation" is adequately understood by a person of ordinary skill in the art and needs no further delineation to meet the requirements of the enablement or written description. It is argued that the insertion of this language is intended to merely provide more elegant language that details the language and idea present in the initial application. It is argued that paragraph 21 provides a standard for ascertaining the degree (i.e. P factors on the other side of thee quantitative spectrum to high correlation).

Applicants' arguments filed March 1 2010 have been fully considered but they are not persuasive.

The correlation claimed and referred to in the claims is the correlation between the test modality and the use of the supplement. While higher correlation is taught, it is not taught that lower correlation is the opposite of higher correlation. This is not a term that was taught in the instant specification. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its

enablement provision. (See page 1115.) The instant specification must provide support for this limitation and the examiner maintains that it does not.

New Rejections Necessitated by the Amendments filed March 1 2010

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-17 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a total lack of enablement rejection.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Formal, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, relative skill level, and breadth of the claims

The instant invention is directed to a method of providing a supplement to a user comprising the steps of: contain an amount of a separate calcium supplement in a distribution container; selecting a plurality of saliva pH test strips that test for a calcium deficiency in a user; etc.

Therefore applicants are claiming that the second step is such that the saliva pH

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[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is

test strips test for a calcium deficiency in a user.

The relative skill of those in the art is high, that of an MD or PHD.

The state and predictability of the art

The state of the art recognizes that calcium deficiency can be measured with a urine test and a blood test. The art also recognizes that pH test strips measure solution acidity on a log scale based on 10. As illustrative of the state of the art, the examiner cites Zumdahl (Chemistry, 1993), Medline Plus (http://www.nlm.nih.gov/medlineplus/ency/article/003603.htm) and The Merck Index (http://www.merck.com/mmhe/print/sec12/ch155/ch155b.html). Zumdahl teaches that the pH scale provides a convenient way to represent solution acidity (page 645). The scale goes from 0 to 14 (acidic to basic) (page 646). pH test strips are indicator paper which can be used to estimate the pH of a solution (page 733). Medline plus teaches that calcium deficiency can be measured with a urine test. The test is a 24 hour urine test. Following which the amount of calcium is determined in the urine. Standards are known based on the users diet to determine whether the amount of urine in the test is high or low (page 2, normal results, page 1 how the test is performed). The Merck index indicates that hypocalcaemia (low calcium levels) can be detected by routine blood test (page 2, diagnosis).

The lack of significant guidance from the specification or the prior art with regard to testing calcium deficiency utilizing pH test strips makes practicing the scope of the invention unpredictable.

"undue", not "experimentation".

Regarding claim 44, the claim requires that the test strip is a pH test strip. As indicated above, pH measures the acidic or basic nature of a solution. The examiner can find no recognition in the art that the measurement of pH can test for a deficiency of any supplement. The instant specification does not provide any correlation between a pH test strip and supplement deficiency.

The amount of direction or guidance provided and the presence or absence of working examples and the quantity of experimentation necessary

The specification provides no direction or guidance for how a pH test strips which measures for acidity or basicity of a solution can be utilized to test for calcium deficiency. The art recognizes that calcium deficiency can be measured with a urine or blood test but not a pH test strip. Furthermore, how the saliva test is performed is not taught. If a user had just drunk milk or just drank a highly acidic soda, this would have an effect on the acidity of the saliva.

There are no working examples that teach how a pH test strip measures for calcium deficiency. Therefore, one of ordinary skill in the art would have to under go excessive experimentation to determine how a pH test strip measures for calcium deficiency.

Conclusions

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the pH test strips can be used to test for calcium deficiency as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with

the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 18-20, 46, 54-69, 73-82, 105-106, 111-113 and 132-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 introduces new matter as the claim recite the limitation: "insulin substance or prescribed medication substance". There is no support in the specification for this limitation. The limitation of: "insulin substance or prescribed medication substance" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses calcium and supplement but does not describe the instantly claimed limitation. There is no guidance in the specification to select insulin and prescribed medication substance and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does

not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

It is noted that in the previous Office action the examiner indicated that specification was enabled, by way of the prior art, for a blood glucose monitor and an insulin (supplement) and a peak expiratory flow device with the appropriately prescribed medication. However, this does not mean that the instant specification provides support for these limitations. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Modified Rejection Based on amendments in the reply filed on March 1 2010

Claim 18-20, 43, 45-46, 54-69, 73-82, 105-106, 110-113 and 132-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The specification (by way of the prior art), while being enabling for a calcium supplement and blood or urine test, a blood glucose monitor and an insulin (supplement) and a peak expiratory flow device with the appropriately prescribed medication does not reasonably provide enablement for a method of making a supplement available containing a separate amount of said supplement and a separate test modality. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention

commensurate in scope with these claims. Specifically, the instant specification has not described or enabled the combination of supplement and test modality other than what is described above.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[2]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Formal, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that

scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, relative skill level, and breadth of the claims

The instant invention is directed to a method of making a supplement available comprising the steps of: containing a separate amount of said supplement by a distribution container; selecting a separate test modality relevant to some aspect in conjunction with use of said supplement; establishing a producer for use of said separate test modality; compactly assembling said separate test modality; and providing said compactly assembled separate test modality for distraction in association with said distraction container.

The complex nature of the claims is greatly exacerbated by the breath of the claims. The instant claims recite any supplement in combination with any test modality. The relative skill of those in the art is high, that of an MD or PHD.

The state and predictability of the art

The state of the art recognizes testing for calcium deficiency via a blood or urine test. As illustrative of the state of the art, the examiner cites Zumdahl (Chemistry, 1993), Medline Plus (http://www.nlm.nih.gov/medlineplus/ency/article/003603.htm) and The Merck Index (http://www.merck.com/mmhe/print/sec12/ch155/ch155b.html), a

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[2] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

glucose monitor in combination with insulin therapy (Beckers US Patent No. 5019974) and a peak expiratory flow rate in combination with prescribed medication (Kaish US Patent No. 5501231). In these cited references the objective of the test and the supplement is clearly indicated. The glucose monitor measures blood sugar levels to indicate when insulin needs to be administered, blood and urine test measure for calcium deficiency and the peak expiratory flow rate machine monitors a patient's respiratory system in combination with the prescribed medication. Zumdahl teaches that the pH scale provides a convenient way to represent solution acidity (page 645). The scale goes from 0 to 14 (acidic to basic) (page 646). pH test strips are indicator paper which can be used to estimate the pH of a solution (page 733). Medline plus teaches that calcium deficiency can be measured with a urine test. The test is a 24 hour urine test. Following which the amount of calcium is determined in the urine. Standards are known based on the users diet to determine whether the amount of urine in the test is high or low (page 2, normal results, page 1 how the test is performed). The Merck index indicates that hypocalcaemia (low calcium levels) can be detected by routine blood test (page 2, diagnosis).

The lack of significant guidance from the specification or the prior art with regard to utilizing any test modality with any supplement makes practicing the scope of the invention unpredictable.

The amount of direction or guidance provided and the presence or absence of working examples and the quantity of experimentation necessary

The specification provides no direction or guidance for utilizing any supplement

with any test modality. The only specific combination taught is pH test strips and calcium supplements. Due to the vastness of compounds classified as supplements, as this term includes herbs, pharmaceuticals, cosmetic active, any ingredient with a biological effect and the vastness of test modalities one of ordinary skill would undergo undue experimentation in deducing which supplements can be used with what particular test modalities within applicant's scope.

There are no working examples in the specification. The descriptions of the particular test modalities suggested by the instant specification and claimed only refer to the test by name. However, this name does not describe the test nor teach one of ordinary skill in the art what the test is actually testing for except for pH test strips as that name provides enough guidance to one of ordinary skill in the art what is actually being tested. In *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 Fed. Cir. 1997 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." (emphasis added). The instant specification provides no guidance as to the correlation between pH test strips and calcium supplements. The specification provides no guidance as to how a pH test strip measures for calcium deficiency. Therefore, one of ordinary skill in the art would have to undergo undue experimentation as they would first have to determine which supplement would be prescribed then determine which test if any can be used in conjunction. This is tantamount to undue burden.

Conclusion

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed supplement can be used in combination with some particular test modality as inferred by the claim and contemplated by the specification. The instant specification provides no guidance as to what the test modalities actually test for nor how they are correlated to supplements. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Response to Arguments

Applicants argue that (1) the claimed invention is not in a new or unpredictable field where in the existing knowledge and prior art was scant. The claims do not invent the deficiency tests, they only set forth applying them in a unique manner.

Applicants' arguments filed March 1 2010 have been fully considered but they are not persuasive.

It is not clear to the examiner how applicants do not believe that they did not invention the deficiency tests. The examiner maintains the art does not recognize a link between calcium deficiency and pH test strips. While the recites claims general recite test strips or test modality the claims link that to any supplement. No specific combinations are taught. . In *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366

Fed. Cir. 1997 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." The instant claims recite a variety of tests but no description is provided as to what the test for. For instance, the claims recite a dye-based test but it doesn't state whether the dye based test measures for a dye or uses a dye in the test. Furthermore, if it measures for a dye how is a dye a calcium supplement, insulin substance or a prescribed medication? Another example is a temperature based test. How does this test measure for calcium supplement, insulin substance or a prescribed medication? Instant claims 132 and 136 recite a variety of tests. How these test measure for deficiency in calcium, insulin or a prescribed medication is not taught. Therefore, one of ordinary skill would have to under go undue experimentation as they would to first determine what these test are, how they work and then determine how they measure for deficiency in calcium, insulin or a prescribed medication

Claims 18-20, 43, 45, 69, 73-82, 105-106, 110-113, 132-134 and 136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses tests, such as pH test strip which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) **43, 45, 69, 73-82, 105-106, 110-113, 132-134 and 136** is(are) directed to encompass **any test modality, test strip, on-site test, send-in test, supplement need indicative test, supplement efficacy based test, user profiled test, the tests of claim 78, qualitative test, semi quantitative test, etc. (those tests of claim 105), personal baseline test, tests of claim 132, saliva sensitive test, urine based test, hair based test, nail based test, non-invasive test, blood-based test, and tests of claim 135 as well as a variety of different procedures such as time of day based procedure, same time of day test procedure, morning based test procedure, etc. (specifically those of claim 69).** None of these tests meet the written description provision of 35 USC § 112, first paragraph, due to any information as to what the test is actually testing for or how its performed and tests are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

The appearance of mere indistinct words in a specification or a claim,

even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing “sufficiently detailed, relevant identifying characteristics,” including “functional characteristics when coupled with a known or disclosed correlation between function and structure.” Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

The instant specification provides no description for what the test is actually testing for. A ph test is a sufficient description for this particular test as a pH range is small enough that one of ordinary skill in the art would know what is being tested. However this is not true for the other tests taught. For example in the AIDS based test,

is the test for determining whether or not someone has AIDS or is it testing for a specific antibody. The specification provides no description for these tests other than the names. Furthermore, the claims recite procedures that are to be performed but the specification provides no description as to what these procedures are or what they are supposed to accomplish. Therefore, only the above specifically described test the pH test strip, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

While Applicants' do not argue the rejection specifically, Applicants argue that the Supreme Court has held that measure of the sufficiency of written description is whether the description enables a skilled artisan to make and use the invention. It is argued that applicant was in possession of the claimed invention by the simple fact that claims 43-45 have been present in the application since the priority PCT case.

Applicants' arguments filed March 1 2010 have been fully considered but they are not persuasive.

While applicants may have had the language of the above rejection claims present in the PCT that does not mean that applicants have described the invention with sufficient specificity to enable one or ordinary skill in the art to make and use the

invention. The instant specification provides no description for what the test is actually testing for. A ph test is a sufficient description for this particular test as a pH range is small enough that one of ordinary skill in the art would know what is being tested. However this is not true for the other tests taught. For example in the AIDS based test, is the test for determining whether or not someone has AIDS or is it testing for a specific antibody. The specification provides no description for these tests other than the names. Furthermore, the claims recite procedures that are to be performed but the specification provides no description as to what these procedures are or what they are supposed to accomplish. Other examples include a temperature-based test, dye based test, hormone based test. The instant specification provides no guidance as to what these test are, what they measure, or even refer to teachings in the art for guidance as to where information of these test can be found.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 105-106, 110-112 and 132-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 105 as currently written is vague and indefinite. The claim recites a variety of different tests such as qualitative test, semi-quantitative test, quantitative test, rate of change test, absolute value test, relative value and fail safe test. However, the instant claim and the specification provide no description or explanation as to what these test

pertain to. The terms qualitative, semi-quantitative, quantitative, rate of change, relative value and fail safe are relative terms which renders the claim indefinite. The term terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant specification provides not explanation as to what differentiate a absolute value test from quantitative, etc. The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for different tests.

Claim 106 as currently written is vague and indefinite. The term "highly correlates" in claim 106 is a relative term which renders the claim indefinite. The term "highly correlates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant claim indicates that a certain correlation is desired however what the correlation is or what amount of correlation would lead to something being highly correlated is not discussed or contemplated.

Claims 110-112 as currently written are vague and indefinite. The term "lower correlation" in claims 110-112 is a relative term which renders the claim indefinite. The term "lower correlation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant claim indicates that a certain correlation is desired however what the correlation is or what amount of

correlation would lead to something having lower correlation is not discussed or contemplated. Furthermore, the instant specification and claims give no guidance as to what distinguishes a test from being lower correlated as opposed to higher correlated.

Claim 132 as currently written is vague and indefinite. The claim recites a variety of different tests. However, neither the instant claim nor the instant specification indicates what these test are actually testing for. For example is a dye based test, testing for a particular dye or is it using a dye for testing. What is a chromatography based test? Is it using chromatography? If so then what does it test for? It is difficult to determine if the tests claimed are utilizing what is described in the name or it is testing for what is used in the name.

Claims 133-134 as currently written are vague and indefinite. The claims recite specific tests. However, it is unclear if the tests are testing for the presence of saliva, urine, hair, nail and blood or if this is location that the test is utilized such as a urine test strip.

Response to Arguments

Applicants argue that (1) the use of claim language of claim 105 are adequately understood by a person of ordinary skill and need no further delineation. It is argued that the understanding are found on page 15 of PCT publication as well as the use of the dictionary. Applicants argue that (2) the language of claims 106 and 110-112 of highly correlates and low correlation are described in the specification at paragraph 21. The paragraph provides a way of ascertaining the degree.

Applicants' arguments filed March 1 2010 have been fully considered but they are not persuasive.

Regarding applicants' first argument, the claim terminology utilized in claim 105 are relative terms. There are different degrees associated with each word. However, the specification and the dictionary do not allow one of ordinary skill to ascertain the degree difference between the terms utilized.

Regarding applicants' second argument, the specification (even paragraph 21) provides no guidance how to determine this correlation. Probability is the likelihood of potential events. How one determines if a test correlates to the use of a substance is not described in the specification. Furthermore, lower correlation is not indicated in the specification as everything but higher correlation. Wouldn't there also be some sort of middle ground. The response indicates that there are only two correlations (high and low). However, the specification does not make this clear. Furthermore, the specification has provided no example of a high correlated test and use as well as a low correlated test and use. While a P factor is discussed how a P factor can measure whether a test modality correlates to the use of a substance is not described.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-20, 43, 45-46, 54-69, 73-82, 105-106, 110-113, 132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckers (US Patent No. 5019974).

Applicant Claims

The instant application claims a method of making a supplement available comprising the steps of: containing a separate amount of a calcium substance, insulin

substance or prescribed medication substance by a distribution container; selecting a separate test modality that tests for a deficiency of one of said substances in a user; establishing a procedure for use of said separate test modality; compactly assembling said separate test modality; and providing said compactly assembled separate test modality for distribution in association with said distribution container.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Beckers is directed to diabetes management system and apparatus. The system and apparatus are for efficient medical control of a medical condition such as diabetes. The system and apparatus comprise a recorder, an interface and a master computer. The master computer develops a program of therapy which is downloaded into the recorder which then remind the patient of any therapy due and records that the therapy has been effected. The recorder is subsequently fed back to the master computer to improve or alert the therapy programme (abstract). The patient enters into the memory of the recorder information relating to insulin types and doses, diet, exercise, urine test results, hypoglycemic reactions and special events. The recorder also incorporates a blood glucose test strip reader and stores the measured value in the memory (column 2, lines 27-37). For insulin therapy there is an alarm that goes off and lets the patient know it is time to take his/her insulin. After the patient has taken the correct dose of insulin, the press the correct key to confirm (column 4, lines 1-29). Other tests include urine test strip for determine urine glucose (column 5, lines 55-64). A blood glucose test strip reader is utilized for determining blood glucose (column 6, lines 63-68). The recorder is used with an interface unit to enable data to be transferred between the

recorder and the master computer (i.e. the data is sent in) (column 9, lines 24-32). A procedure for using the test is taught (columns 5-6, lines 67-68 and 1-11). Print-outs of the blood-glucose values, insulin values, etc. can be generated via the interface with either phone-modem communication or direct communication (column 10). The recorder prompts the patient to perform the actions according to the program at the appropriate time (column 2, lines 27-35). For blood glucose reading a patient inserts a clean strip for a baseline then blood is introduced to the strip and recorded. Times for the test listed include up to 60 seconds and up to 120 seconds (column 6, lines 19-35).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Beckers does not specify making the diabetes management system and apparatus available in conjunction with the insulin. However, the management system and apparatus are designed to be utilized with insulin therapy.

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to make the diabetes management system and apparatus available at the same time insulin is distributed. One of ordinary skill in the art would have been motivated to make the insulin available with the system as the system is designed to be utilized with insulin therapy to help the patient manage their diabetes. Furthermore, one of the steps of the procedure of the system is to alert the patient to take their insulin and then record the results. Therefore Beckers suggest utilizing the system in combination with insulin.

Regarding the no-cost increment, this is design choice. Whether or not the seller charges for the system when it is going to be utilized in combination with insulin does not result in a patentable distinguishing.

Regarding claims 57-58, since both urine and blood glucose are different test methods taught, a multiple test regimen is taught.

Regarding claims 60-64, the test strips provide a way to manual record the test. Then the information can be transmitted to a separate commuter (i.e. internet based system) where results can be tracked and printed out.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) Beckers is only a diabetes management system and does not involve supplying an attached or assembled test item with a supplement or medication.

Applicants' arguments filed March 1 2010 have been fully considered but they are not persuasive.

Firstly it is noted that the above rejected claims do not require that the test is a test strip. So applicants argument that the cited prior art does not teach utilizing test strips is not persuasive.

The system of Beckers is designed to be utilized with insulin therapy to help the patient manage their diabetes. The examiners maintains it would have been obvious to one of ordinary skill in the art to assembly insulin therapy with the system of Beckers as they are designed to be used together.

Claims 18-20, 43, 45-46, 54-69, 73-82, 105-106, 110-113, 132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaish (US Patent No. 5501231).

Applicant Claims

The instant application claims a method of making a supplement available comprising the steps of: containing a separate amount of a calcium substance, insulin substance or prescribed medication substance by a distribution container; selecting a separate test modality that tests for a deficiency of one of said substances in a user; establishing a procedure for use of said separate test modality; compactly assembling said separate test modality; and providing said compactly assembled separate test modality for distribution in association with said distribution container.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kaish is directed to a patient operated instrument and method for testing and recording a biological condition of the patient. The system measure the forced peak expiratory flow of air expelled by the patient when blowing into a measuring tube (column 1, lines 8-14). The method of using the system is wherein the patient presses on button through and the system goes through a self test, if the test is unsuccessful the

system will prompt the user to change the system batteries for powder supply or signal the operator that the device should be returned. After blowing into the tube the system will measure the signal to see if it is acceptable. After three good results are obtained the processor process the biological data stored in memory and indicates that the test has been completed (column 6, lines 1-30). The system lets the patient known that it is time for the test by the means of an alarm. Before shutting down the system can remind the patient to take the prescribed medication and displays the dosages thereof that have been preprogrammed by the doctor (column 7, lines 12-35). Figure 6 shows how the system is used in a physician's office to download the stored biological data and tie data into the physician's personal computer for subsequent analysis and printing (column 7, lines 63-65).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Kaish does not specify making the system available in conjunction with the prescribed medication. However, the system is designed to be utilized with medication.

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to make the system available at the same time the medication is distributed. One of ordinary skill in the art would have been motivated to make the medication available with the system as the system is designed to be utilized with medication to help the patient manage their respiratory status. Furthermore, one of the

steps of the procedure of the system is to alert the patient to take their medication. Therefore Kaish suggests utilizing the system in combination with the medication.

Regarding the no-cost increment, this is design choice. Whether or not the seller charges for the system when it is going to be utilized in combination with insulin does not result in a patentable distinguishing.

Regarding claims 57-58, since three tests are taken at a time, a multiple test regimen is taught.

Regarding claims 60-64, the device itself provides a way to manual record the test. Then the information can be transmitted to a separate commuter (i.e. internet based system) where results can be tracked and printed out.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that Kaish is a test after which one can take their prescribed medication. It is does not describe the medication and a distribution container.

Applicants' arguments filed March 1 2010 have been fully considered but they are not persuasive.

Firstly it is noted that the above rejected claims do not require that the test is a test strip. So applicants argument that the cited prior art does not teach utilizing test strips is not persuasive.

The examiner maintains it would have been obvious to one of ordinary skill in the art to administer the medication with the system of Kaish. The system is designed to be utilized with medication to help the patient manage their respiratory status. Furthermore, one of the steps of the procedure of the system is to alert the patient to take their medication. This provides the motivation to one of ordinary skill in the art to administer the two together.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616